Message

From: Milewski, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2B431A94379440EAA4348D0A4408AF2F-EMILEWSK]
Sent: 1/5/2017 3:58:35 PM
To: Aranda, Amber [aranda.amber@epa.gov]
Subject: RE: GAO
Attachments: GAO response on zika questions - specific to GM - ala v2 emv2 (003) 01 05 2017.docx

Hi, Amber. Here is what I am thinking about for the whole text of the response to question 9.

From: Aranda, Amber
Sent: Thursday, January 05, 2017 10:07 AM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Subject: Re: GAO

thanks. I'm on a conference call for the next hour. I'll try to reach you after.

From: Milewski, Elizabeth
Sent: Thursday, January 5, 2017 10:03:58 AM
To: Aranda, Amber
Subject: RE: GAO

H **Ex. 6 Personal Privacy (PP)**

I did not intend to delete any text. I simply wanted to get a sense if the reorganization of the first part made sense to you and Chris. I'll pull up the whole text and reorganize it so you can see what the whole would look like. Send it to you in a few minutes.

Ex. 6 Personal Privacy (PP)

From: Aranda, Amber
Sent: Thursday, January 05, 2017 9:16 AM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Subject: Re: GAO

Elizabeth - I'm working from home today. And I can't remember your phone number. Can we walk through your proposed text? I'm wondering why you deleted some of your text.

I **Ex. 6 Personal Privacy (PP)**

From: Milewski, Elizabeth
Sent: Wednesday, January 4, 2017 3:07:55 PM
To: Aranda, Amber
Cc: Kaczmarek, Chris
Subject: RE: GAO

Hi, Amber. Thanks for double tasking on this. My issue is that the statement may be historically accurate and accurate today January 4, 2017, but as each day goes by becomes less and less accurate as the situation changes. By the time GAO actually sits down to work on this material, the statement may not be accurate at all. FDA has its documents 236 and 187 in OMB clearance. I am told they anticipate publishing their NOAs on their proposals middle next week.

If Chris insists that we should indicate why EPA did not take the lead back in 2012 (or whenever), can we at least make sure that the language reflects the changing situation? How about a response to question 10a like:

> Originally, FDA asserted jurisdiction over the Oxitec mosquito as a "new animal drug" and because FIFRA excludes new animal drugs from the definition of "pesticide" EPA concluded it had no regulatory authority over the mosquito. Recently, FDA and EPA have committed, along with USDA, to examining their regulatory structures with the goal of clarifying how the Federal government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products. The agencies are working to better align their responsibilities over genetically engineered insects with their traditional oversight roles, for example, considering mechanisms that would enable EPA to regulate genetically engineered mosquitoes under FIFRA when the developer claims they are intended to control population levels (pesticidal), and FDA to regulate them under FD&C Act when the developer makes a disease claim (animal drug). (National Strategy for Modernizing the Regulatory System for Biotechnology Products at https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf). FDA and EPA are currently coordinating their efforts to meet this commitment as both FDA and EPA regulate products intended for use in or on animals. FDA is charged with protecting the public health by, among other things, ensuring that animal drugs are safe and effective [21 U.S.C. §393(b)(2)(B)]; under FIFRA, EPA is charged with protecting human health and the environment by ensuring registered pesticide products, when used according to the label directions, result in no unreasonable adverse effects to man or the environment. [7 U.S.C. § 136a(c)(5)].

From: Aranda, Amber
Sent: Wednesday, January 04, 2017 2:02 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Subject: FW: GAO

Elizabeth – I've been exchanging w Chris on email while on the call. He's not comfortable w a response that fails to take the position as stated in the first sentence given the accuracy and the need to otherwise ensure that the GAO understands why EPA has not taken leadership/the initiative w this one. If needed we can schedule a call w you. Just let me know your preference.

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From: Aranda, Amber
Sent: Wednesday, January 04, 2017 12:08 PM
To: Wozniak, Chris <wozniak.chris@epa.gov>; Johnson, Amaris <Johnson.Amaris@epa.gov>
Cc: Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; McNally, Robert <Mcnally.Robert@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: RE: GAO

Chris and Amaris – A few quick edits on the points below – in the attached redline/strikeout – related to FDA v our authorities.

Amber L. Aranda
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E: aranda.amber@epa.gov

From: Wozniak, Chris
Sent: Wednesday, January 04, 2017 10:34 AM
To: Johnson, Amaris <Johnson.Amaris@epa.gov>
Cc: Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; McNally, Robert <Mcnally.Robert@epa.gov>; Aranda, Amber <aranda.amber@epa.gov>; Kough, John <Kough.John@epa.gov>
Subject: RE: GAO

Hi Amaris,

Please see our response to question #10 from the GAO query. Let me know if you have any questions.

Thanks

Chris
Chris A Wozniak, Ph.D.
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Genetically-Modified Work

1. What rationales underlie the decision for the FDA to oversee genetically-modified mosquitoes?
    a. In particular, why was the FDA – rather than the EPA – doing the environmental assessment?
        i. The EPA, CDC and FDA all worked in coordination on the environmental assessment and finding of no significant impact documents for the Oxitec, Ltd OX513A genetically engineered *Aedes aegypti* mosquito. EPA and FDA-CVM work under a memorandum of understanding to specifically address the assessment of the Oxitec product. While FDA has taken the lead in reviewing this genetically engineered mosquito, EPA and CDC have acted as technical consultants on the assessment.
    b. Does the EPA agree with the FDA conclusion that investigational use of the Oxitec mosquitoes "would not result in significant effects on the quality of the human environment?"
        i. Yes, the EPA Office of Pesticide Programs has signed off on the documents indicating that the environmental field evaluation of the OX513A mosquito as proposed is adequate to allow for field testing. EPA-OPP is in agreement with FDA-CVM and CDC on

the primary finding of the EA and FONSI. We do not feel any significant effects on human health or environmental impact will result from the field testing as described.

c. What is the extent of coordination the EPA and FDA on Oxitec mosquitoes, given the EPA's experience in other GM pest control work?

   i. EPA and FDA maintain a close coordination via meetings, conference calls and e-mail exchange on matters associated with the regulation of the OX513A mosquito. FDA-CVM, CDC and EPA-OPP personnel all commented on drafts of the EA and FONSI documents followed by conference calls to establish final edits for the documents. EPA has attended meetings with Oxitec, FDA-CVM and CDC to discuss the details of the product and the proposed field trial. It should be noted that the FDA and EPA have committed, along with USDA, to examining their regulatory structures with the goal of clarifying how the Federal government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products. The agencies are working to better align their responsibilities over genetically engineered insects with their traditional oversight roles, for example, considering mechanisms that would enable EPA to regulate genetically engineered mosquitoes under FIFRA when the developer claims they are intended to control population levels (pesticidal), and FDA to regulate them under FD&C Act when the developer makes a disease claim (animal drug). (National Strategy for Modernizing the Regulatory System for Biotechnology Products at https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf). FDA and EPA are currently coordinating their efforts to meet this commitment as both FDA and EPA regulate products intended for use in or on animals. FDA is charged with protecting the public health by, among other things, ensuring that animal drugs are safe and effective [21 U.S.C. §393(b)(2)(B)]; under FIFRA, EPA is charged with protecting human health and the environment by ensuring registered pesticide products, when used according to the label directions, result in no unreasonable adverse effects to man or the environment. [7 U.S.C. § 136a(c)(5)].

From: McNally, Robert
Sent: Wednesday, December 28, 2016 5:12 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>
Cc: Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>
Subject: FW: GAO

Can one of you take a cut at Question #10?

From: Johnson, Amaris
Sent: Wednesday, December 28, 2016 5:07 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Hollis, Linda <Hollis.Linda@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Tapken, Wiebke <Tapken.Wiebke@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>

Cc: Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>
Subject: RE: GAO

Hi Bob,
Yes please- we appreciate BPPD handling Q#9 on GE mosquitoes.
I'll include John Leahy on the meeting invite.
Thank you,
Amaris

From: McNally, Robert
Sent: Wednesday, December 28, 2016 4:33 PM
To: Johnson, Amaris <Johnson.Amaris@epa.gov>; Laws, Meredith <Laws.Meredith@epa.gov>; Hollis, Linda <Hollis.Linda@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Tapken, Wiebke <Tapken.Wiebke@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Cc: Hartman, Mark <Hartman.Mark@epa.gov>; Leahy, John <Leahy.John@epa.gov>
Subject: GAO

Amaris – BPPD has added some language for the questions you asked about.

Do you want us to handle question #9 on GE Mosquitoes?

John Leahy would be our choice for next week's meeting.

Bob

GAO Detailed Questions for EPA
Zika Audit (JC#100946)
December 22, 2016

EPA Role

1. What is the role of EPA in U.S. mosquito control?
    a. Does the EPA do active outreach and/or education regarding mosquito control?
    b. What role does the EPA have in encouraging no-chemical mosquito control and the adoption of integrated pest management methods?
2. What challenges does the EPA face in overseeing mosquito control in the U.S.?

Pesticides

3. Can the EPA provide a list of actively used pesticides for mosquito control in the U.S. (document request)?
    a. Does the EPA track pesticide use by individual U.S. mosquito control entities?
    b. Are Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and National Pollution Discharge Elimination System (NPDES) the current requirements for pesticide use documented by the EPA? Are there any other requirements?
    c. What is being protected by these requirements? For example: water purity, air quality, skin contact with sprayed surfaces, or other considerations.

4. How does the EPA determine whether use of pesticides, consistent with labeling, causes unreasonable adverse effects on the environment? We understand the registrant for the pesticide has to provide data demonstrating no such effects. What we'd like to understand better is how EPA determines whether the data satisfies the guidelines (for example, the series 800 test guidelines) and what effects may not be covered by these guidelines.
    a. Is the process the same for existing as well as new pesticides?
    b. What specific considerations are there for biologically-based pesticides such as BTi (bacillus thuringiensis)?
    c. What factors are used to determine the amount or concentration of pesticide to apply? For example, do pesticide application amounts change with air relative humidity or dew point?

One factor used to determine the application rate of a pesticide is product efficacy. Efficacy data are submitted or cited to support the use of a pesticide product at the lowest labeled rate for all labeled public health pests, including mosquitoes. These data are evaluated to determine if product is efficacious against public health pests when applied as labeled. Pesticides are also evaluated to ensure that, when applied at the labeled application rate, they do not pose unreasonable adverse effects to the humans or the environment.

        i. How do these factors change if adjacent mosquito control entities wish to apply pesticides? For example, is there any accounting for wind or overdosing near the borders?
    d. Does the EPA monitor or otherwise assess compliance by mosquito control entities to EPA regulations?
5. Can the EPA provide a list of pesticides that are currently being evaluated for mosquito control (document request)? These may include modified use of existing pesticides– such as at different concentrations or different means of distribution – or new pesticides.

~~We can provide such a list but~~ At this time the EPA has ~~only one~~ the following actions in-house.

a. ~~This is~~ a request ~~in~~ to expand the use of etofenprox impregnated clothing label from just military use to consumer use.
b. Request for a new product containing P-menthane diol, a biochemical pesticide, as a dermally applied insect repellent claiming to control the Zika, Dengue and West Nile virus(s).
c. Request for a PRIA amendment containing IR3535, a biochemical pesticide, as a dermally applied insect repellent to add claims for the control the Zika, Dengue and West Nile virus(s).
d. Request for three (3) fast track amendments containing *Nepeta cataria*, a biochemical pesticide, as a dermally applied insect repellent to add claims for the control the Zika, Dengue and West Nile virus(s).
e. Request for four (4) fast track amendments containing IR3535, a biochemical pesticide, as a dermally applied insect repellent to add claims for the control the Zika, Dengue and West Nile virus(s).
f. Request for one (1) fast track amendment containing lactic acid, amonium bicarbonate and hexanoic acid, all biochemical pesticides, as a sachet repellent to be used with mosquito lure traps for the control the Zika, Dengue and West Nile virus(s).
g. Request for one (1) fast track amendment containing p-methane diol, a biochemical pesticide, as a towelette repellent to add claims for the control the Zika, Dengue and West Nile virus(s).
h. Registration of a new active ingredient, *Wolbachia pipientis* ZAP Strain, a microbial pesticide designed to prevent successful reproduction among *Aedes albopictus* mosquitoes.

6.

7. Does the EPA perform, or provide guidance to mosquito control entities for performing, assessments of whether pesticides are effective?
    a. How, if at all, does the EPA monitor pesticide resistance?
8. Are there specific considerations for pesticide applications for the Aedes mosquitoes in particular?

Our current policy is that in order to make a general claim against mosquitoes on a pesticide label, efficacy data should be submitted on three specific genera of mosquito and should show that the product is efficacious at the lowest labeled rate for all three genera. In addition to data on *Culex* and *Anopheles*, data should also be submitted on either *Aedes albopictus* or *Aedes aegypti*.
For the *Wolbachia pipientis* ZAP strain, the nature of the pesticide product, releasing male *Aedes Albopictus* mosquitoes infected with this strain of bacteria, thereby preventing successful mating with native female mosquitoes, raises novel issues for the Agency to consider.

Clean Water Act

9. How is the permitting process for FIFRA different from that of the NPDES?
    a. In particular, what does the NPDES require that wasn't required by the FIFRA?
        i. Do the NPDES requirements lead to environmental protection that would not be covered by FIFRA?
            1. Is the EPA aware of any documented reduction in pesticide use for mosquito control since the implementation of the program in 2011 (document request)? We note that EPA states in the 2016 EPA NPDES 2016 Pesticide General Permit Response to Public Comments that among other things, the EPA expects benefits resulting from minimization of pesticide discharge to U.S. waters.
            2. Has the EPA documented any change to water quality resulting from the implementation of the NPDES program (document request)?
            3. Is the EPA aware of any adverse incidents reported under the NPDES that would not have been reportable under the FIFRA?
            4. Is the EPA aware of changes to mosquito control districts resulting from the NPDES program requirements, such as district closure, or threats of lawsuits?
    b. What was the EPA rationale for not appealing the 6th Circuit Court of Appeals decision?

Genetically-Modified Work

10. What rationales underlie the decision for the FDA to oversee genetically-modified mosquitoes?
    a. In particular, why was the FDA – rather than the EPA – doing the environmental assessment?
    b. Does the EPA agree with the FDA conclusion that investigational use of the Oxitec mosquitoes "would not result in significant effects on the quality of the human environment?"
    c. What is the extent of coordination the EPA and FDA on Oxitec mosquitoes, given the EPA's experience in other GM pest control work?